

651 CMR 15.00: PRESCRIPTION DRUG INSURANCE PLAN

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15.01: Introduction

St. 2000, c. 159, §§ 46, 47, 406 and 497 (as amended by St. 2001, c. 177, § 11) direct the Executive Office of Elder Affairs to develop and administer a voluntary catastrophic prescription drug insurance plan designed to provide eligible persons with prescription drug insurance coverage, effective April 1, 2001. The name of the prescription drug insurance plan is Prescription Advantage (the Plan). The Plan is subject to appropriation. Ch. 45 of the Acts of 2005, § 27 directs that, for Members in the Plan who qualify for Medicare Part D and who are at specified levels of income, the Plan shall provide supplemental assistance for premiums, deductibles, payments and co-payments required by the Member's Medicare Part D Plan.

15.02: Definitions

Administrative Review— the final level of review upon the timely request of a Member or Applicant, or his or her designee, of decisions made by the Plan to deny or terminate enrollment, Plan determinations of a Member's Gross Annual Household Income, or decisions by the Plan to deny or limit Covered Benefits, including Supplemental Assistance.

Administrative Review Officer – an employee or agent of Elder Affairs who conducts Administrative Reviews.

Applicant – an individual who has completed and submitted an application form that has been received by the Plan, and who is awaiting a determination of eligibility.

Brand-Name Drug – a Prescription Drug that receives patent protection for its name, chemical formulation and/or manufacturing process, and is approved by the Food and Drug Administration (FDA).

Business Day – a day during which Elder Affairs is open to the public during regular business hours. If the last day of a time period set forth in 651 CMR 15.00 falls on a day during which Elder Affairs is closed to the public, the last day of the time period shall be deemed to be the next Business Day.

Co-insurance – the amount of money that a Member pays to a Participating Pharmacy or approved mail order facility, based on a percentage of the cost of a Prescription Drug as determined by the Member's Medicare Prescription Drug Plan.

CommonHealth – a MassHealth program administered by the Office of Medicaid to furnish and pay for medical benefits to eligible individuals pursuant to M.G.L. c. 118E, §§ 9A, 16 and 16A and the regulations promulgated thereunder.

Commonwealth – the Commonwealth of Massachusetts.

Co-payment – the applicable point of purchase contribution established by the Plan and paid by a Member to a Participating Pharmacy or approved mail service facility for each Prescription Drug dispensed.

Covered Benefits – items listed on the Plan Formulary. Covered Benefits include Prescription Drugs that are on the Plan Formulary, are dispensed by a retail pharmacy (including mail service) and can be self administered. Covered benefits do not include any Prescription Drugs that are administered in an inpatient setting. For any Member who is enrolled in a Medicare Part D Plan or Creditable Coverage Plan, covered benefits are only those products that are covered by the Member's Part D Plan or Creditable Coverage Plan and benzodiazepines.

Creditable Coverage Plan – a plan which provides creditable prescription drug coverage as defined by Section 104 of the MMA, and which provides coverage for the cost of prescription drugs actuarially equal to or better than that provided by Medicare Part D.

Deductible – the amount of money paid by a Member toward Covered Benefit costs prior to gaining access to Covered Benefits at the applicable Co-payment rates.

Elder Affairs – the Massachusetts Executive Office of Elder Affairs (also called the Department of Elder Affairs).

Effective Date of Coverage – the date on which a Member is eligible to receive Covered Benefits.

Enrollment – the process during which the Plan accepts application forms for the purpose of review, determination of eligibility, and approval of Applicants to receive Covered Benefits.

Enrollment Fee – an annual fee a member is required to pay to receive Covered Benefits or Supplemental Assistance under the Plan.

Federal Poverty Level – the national poverty income guidelines applicable to Massachusetts. Said guidelines are issued annually in the Federal Register by the Secretary of the Department of Health and Human Services to account for changes in the cost of living as measured by the change in the average annual value of the Consumer Price Index.

Fiscal Year – the annual accounting period employed by the Commonwealth, beginning on July 1 and ending on June 30 each year.

Generic Drug – a Prescription Drug that is: approved by the Food and Drug Administration (FDA); bio-equivalent to a Brand-Name Drug; produced by one or more drug companies under its generic name; and available on the Plan Formulary at the lowest Co-payment level.

Gross Annual Household Income – the amount of total income as reported on federal income tax returns and any additional Social Security income as reported on form(s) SSA-1099 for the Applicant or Member and, if they live together in the same housing unit, the Applicant's or Member's Spouse. For Applicants or Members not required to file a federal income tax return, Gross Annual Household Income includes the total amount of money, earned or unearned, from any source, including, but not limited to, wages, salaries, rents, pensions, dividends and interest received by each Applicant or Member and his or her Spouse.

Household – a single adult or married couple, and any other relatives who depend on that adult or couple to provide at least one half of their financial support, and who live together in the same housing unit.

Low-income Subsidy – financial assistance provided by Medicare pursuant to the MMA Subpart P to Members who qualify for payment of Medicare Part D premiums and other cost-sharing associated with drug coverage, as defined in 42 C.F.R. 423.780 and 423.782.

Maintenance Drug – a Prescription Drug prescribed to an individual for a chronic condition, the use of which is medically necessary for a period of ninety (90) consecutive calendar days or longer.

MassHealth – the medical assistance or benefit program administered by the Office of Medicaid pursuant to Title XIX of the Social Security Act (42 U.S.C. §1396), Title XXI of the Social Security Act (42 U.S.C. §1397), M.G.L. c. 118E, and other applicable laws and waivers.

Medicare Advantage Prescription Drug Plan (MA-PD) – a Medicare Advantage plan that provides qualified prescription drug coverage.

Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) – the federal law enacted to provide a prescription drug benefit to Medicare-eligible citizens.

Medicare Part D – the Medicare prescription drug program available to Medicare beneficiaries beginning January 1, 2006.

Medicare Part D Covered Drug – prescription drugs, biological products, insulin and medical supplies associated with the injection of insulin, and vaccines licensed under section 351 of the Public Health Service Act, that meet the definition of a covered part D drug as set forth in the MMA.

Medicare Part D Plan – a Medicare-approved Prescription Drug Plan, a Medicare Advantage Prescription Drug Plan, and, where the context requires, a Creditable Coverage Plan.

Medicare Part D Plan Formulary – a list of Prescription Drugs covered by an individual Medicare Part D Plan, and the applicable co-payment levels.

Medicare Prescription Drug Plan (PDP) – a prescription drug plan that provides prescription drug coverage through a PDP sponsor that is under contract with CMS, and offered under a policy, contract, or plan that has been approved under 42 C.F.R. §423.272.

Member – an Applicant who is determined eligible to receive Covered Benefits or Supplemental Assistance under the Plan.

Membership Categories – categories established by the Plan, based on Members' Medicare Part D coverage, coverage under a Creditable Coverage Plan, Gross Annual Household Income, and eligibility for the Medicare Low-income Subsidy. Specific benefit levels will apply to members in each category, including Enrollment Fees, Co-Payments, Deductibles, Supplemental Assistance, and Annual Out-Of-Pocket Spending Limits.

Non-Preferred Drug (Level 3 Drug) – a Brand Name Drug available on the Plan Formulary at the highest Co-payment level. For Members who are eligible for Medicare Part D, each Medicare Part D Plan will establish its own co-payment levels.

Open Enrollment – a period of time as determined by the Secretary during which the Plan will accept application forms from Applicants age 66 or over pursuant to 651 CMR 15.05(4).

Out-of-Pocket Expenditures – the total amount paid by a member to satisfy his or her applicable Plan Co-Payments and Deductibles, not including Premiums. For members of a Medicare Part D Plan, out-of-pocket expenditures include the total amount paid by a Member to satisfy his or her Medicare Part D Co-payments, Co-insurance, and Deductibles pursuant to the Medicare Part D Plan, but do not include Premiums.

Out-of-Pocket Spending Limit – a cap on the amount that a Member must pay to satisfy his or her own applicable Plan Co-Payments, Co-insurance, and Deductibles. The Plan shall establish this limit on an annual basis.

Participating Pharmacy – any registered pharmacy that has agreed to comply with the requirements, reimbursement methods and rates established by the Plan.

Plan Formulary – a list of Prescription Drugs, including insulin and disposable insulin syringes with needles issued by Prescription, covered by the Plan. For Members enrolled in a Medicare Part D Plan, each Medicare Part D Plan will have its own list of Prescription Drugs, biological products, insulin, and medical supplies covered by that Medicare Part D Plan, define whether they are classified as generic or brand name drugs.

Plan Year – the annual period of Plan operations beginning on July 1 and ending on June 30 each year. As of January 1, 2006, the Plan Year will be the annual period of Plan operations beginning on January 1 and ending on December 31. To enable this change, the period July 1, 2005 through December 31, 2005 will be considered a separate Plan Year.

Preferred Drug (Level 2 Drug) – a Brand Name Drug available on the Plan Formulary at a Co-payment level between a Generic Drug and a Non-Preferred Drug. Each Medicare Part D Plan will establish its own co-payment levels.

Premium – the amount a Member is required to pay to the Plan per month to receive Covered Benefits under the Plan.

Prescription – an order for a drug, either written, given orally or otherwise transmitted to a registered pharmacy by a licensed practitioner with prescriptive privileges granted by an appropriate licensing authority, or his or her expressly authorized agent.

Prescription Advantage (the Plan) – the catastrophic Prescription Drug insurance plan created by St. 2000, c. 159, §46, *et seq.* which is administered by Elder Affairs and carried out by entities under agreement with Elder Affairs.

Prescription Drug – any and all outpatient drugs approved by the Food and Drug Administration (FDA) which, under federal law, are required, prior to being dispensed or delivered, to be labeled with the statement “Caution, Federal law prohibits dispensing without prescription” or a drug which is required by any applicable federal or state law or regulation to be dispensed only by Prescription.

Prior Authorization – the process by which the Plan requires additional information to determine if certain Prescription Drugs are Covered Benefits. For Members enrolled in a Medicare Part D Plan, the Member’s Medicare Part D Plan will define any Prior Authorization process.

Reconsideration – the process by which a designated Plan representative evaluates decisions made by the Plan upon the timely request of an Applicant or Member or their designee.

Resident – A person who lives in the Commonwealth with the intent to remain permanently or for an indefinite period of time and, whenever absent, intends to return to the Commonwealth.

Review – the appeal process of the Plan, as set forth in 651 CMR 15.15, that consists of Reconsideration and Administrative Review.

Secretary – the Secretary of the Executive Office of Elder Affairs

Supplemental Assistance – financial assistance provided by Prescription Advantage for premiums, deductibles, payments, co-payments and co-insurance required by a Member's Medicare Part D Plan; or for deductibles, payments, co-payments and co-insurance required by a Member's Creditable Coverage Plan.

Therapeutically Equivalent Prescription Drug – a Prescription Drug that is of the same pharmacological or therapeutic class as another Prescription Drug and can be expected to have a similar therapeutic effect when administered in therapeutically equivalent dosages.

15.03: Covered Benefits

(1) Plan Members are eligible to receive Covered Benefits subject to their compliance with the payment specifications under 651 CMR 15.07.

(2) Covered Benefits include Prescription Drugs that are on the Plan Formulary, are dispensed by a retail pharmacy (including mail service) and can be self-administered. Covered Benefits do not include any Prescription Drugs that are administered in an inpatient setting. For Members enrolled in a Medicare Part D Plan or Creditable Coverage Plan, Covered Benefits are only those products that are covered by the Medicare Part D Plan or Creditable Coverage Plan in which the Member is enrolled and benzodiazepines.

(3) Access to Covered Benefits shall not commence until the Effective Date of Coverage. No Prescription Drug procured by a Member prior to the Effective Date of Coverage shall be considered a Covered Benefit.

(4) Covered Benefits include items not on the Plan Formulary only when approved for coverage pursuant to Review procedures set forth in 651 CMR 15.15.

(5) To ensure appropriate use of Covered Benefits, the Plan may require Prior Authorization and may use benefit management tools, including quantity limitations for certain Prescription Drugs. For Members enrolled in a Medicare Part D Plan, any Prior Authorization process will be defined and conducted by the Member's Medicare Part D Plan.

15.04: Eligibility

(1) A Member of the Plan must be a Resident of the Commonwealth who is not eligible for MassHealth and:

- (a) i. is 65 years of age or older and is not eligible for Medicare, or
- ii. is 65 years of age or older and is eligible for Medicare and has Gross Household Income less than or equal to 500 percent of the poverty guidelines updated periodically in the Federal Register by the U.S. Department of Health and Human Services; or

- (b) has a Gross Annual Household Income less than or equal to the Plan's designated percentage of the Federal Poverty Level for full Plan contribution toward Premiums and Deductibles, does not work more than 40 hours per month and meets:
1. the disability requirement of the CommonHealth program as referenced under M.G.L. c. 118E, §9A, subsection (2), clause (h), notwithstanding the income eligibility requirements under M.G.L. c. 118E, §9A, subsection (2), clause (h); or
 2. the disability requirements of the CommonHealth program as referenced under M.G.L. c. 118E, § 16, notwithstanding the income eligibility requirement under M.G.L. c. 118E, §9A, subsection (2), clause (h); or
 3. the disability requirements of the CommonHealth program as referenced under M.G.L. c. 118E, § 16A; or
- (c) was enrolled in the Pharmacy Program (M.G.L. c.118E, §16B), or Pharmacy Program Plus (St. 1999, c. 127 § 313, as amended by St. 2000, c. 159 § 2, line item 4000-1450) as of March 31, 2001.

(2) The Plan may require verification or re-verification of any eligibility requirement at any time.

(3) Beginning January 1, 2006, in order to be eligible for the Plan, individuals who are eligible for Medicare must be enrolled in a Medicare Part D Plan. All Applicants and Members who may qualify for the Low-income Subsidy shall apply for that subsidy.

15.05: Enrollment

(1) Enrollment in the Plan is voluntary and available to all persons eligible under 651 CMR 15.04, unless a determination is made by the Secretary to close Enrollment.

(2) The Secretary shall close Enrollment or an established Open Enrollment period after making a written determination that Plan expenditures are projected to exceed the amount appropriated for the Plan. Such determination may also be made if, based on not less than nine months of claims and enrollment data for the current Fiscal Year, expenditures in the subsequent Fiscal Year are clearly projected to annualize beyond the expenditures projected by the Secretary in the subsequent Fiscal Year.

(3)Initial Enrollment.

- (a) Persons eligible under 651 CMR 15.04(1)(b) may join or re-join the Plan at any time.
- (b) Persons eligible under 651 CMR 15.04(1)(c) must be enrolled in the Plan by March 31, 2002 in order to preserve said eligibility. After March 31, 2002 such persons may join or re-join only if eligible under 651 CMR 15.04(1)(a) or 651 CMR 15.04(1)(b).
- (c) Persons eligible under 651 CMR 15.04(1)(a) may join the Plan as follows:
1. at any time during the period beginning April 1, 2001 and ending on March 31, 2002;
 2. beginning April 1, 2002, persons who are 65 and are eligible under 651 CMR 15.04(1)(a) may join the Plan at any time prior to their 66th birthday;
 3. beginning April 1, 2002, persons eligible under 651 CMR 15.04(1)(a) who have reached age 66 and have not previously joined the Plan, may join, provided that they

apply for enrollment in the Plan within six (6) months after the occurrence of one of the following:

- a. the establishment of residency in the Commonwealth;
- b. the loss of employer-sponsored health care coverage because:
 - i. employment ends,
 - ii. an employer stops health care coverage for active or retired employees,
 - iii. the employer-sponsored health care coverage ends due to insolvency, bankruptcy or involuntary termination of coverage, or
 - iv. the employee's eligibility for coverage pursuant to the provisions of the Consolidated Omnibus Budget Reconciliation Act of 1986 (COBRA) ends;
- c. loss of non-group health care coverage due to insolvency, bankruptcy or involuntary termination of coverage;
- d. loss of Medicare managed care plan because the Medicare managed care plan ceases service for the geographic area in which the person resides;
- e. loss of MassHealth pharmacy benefits;
- f. eligibility for a Medicare Initial Enrollment Period because of becoming eligible for Medicare;
- g. eligibility for a Medicare Special Enrollment Period for Part D because of involuntary loss of creditable coverage; or
- h. loss of eligibility for Medicare full subsidy status due to change in income or assets.

(d) In the event that the Secretary closes Enrollment, no one shall be allowed to apply for initial enrollment until Enrollment re-opens.

(4) Open Enrollment.

- (a) The Secretary shall establish an annual Open Enrollment. The first such Open Enrollment shall commence not earlier than April 1, 2002.
- (b) Persons eligible under 651 CMR 15.04(1)(a) who do not join under 651 CMR 15.05(3)(c) may join only during Open Enrollment.
- (c) Any such Open Enrollment shall be for a period of at least one month, unless the Secretary makes a written determination that Plan expenditures are projected to exceed the amount appropriated for the Plan.
- (d) Persons eligible under 651 CMR 15.04(1)(a) whose Gross Annual Household Income exceeds the Plan's designated percentage of the Federal Poverty Level for full Plan contribution toward Premiums and Deductibles and who do not join pursuant to 15.05(3)(c) may be subject to a surcharge.
- (e) In the event that the Secretary closes Enrollment, no annual Open Enrollment shall be established until Enrollment re-opens.

(5) Re-Enrollment.

- (a) Except for those persons eligible under the criteria set forth in 651 CMR 15.04(1)(b), who may apply for re-enrollment at any time, a Member who voluntarily terminates enrollment may apply for re-enrollment in the Plan only during the period beginning

April 1, 2001 and ending on March 31, 2002 or during Open Enrollment with the following exceptions:

1. Persons who have experienced the loss of employer-sponsored health care coverage may apply for re-Enrollment in the Plan within six months of the occurrence of one of the following:
 - a. employment ends; or
 - b. an employer stops health care coverage for active or retired employees; or
 - c. the employer-sponsored health care coverage ends due to insolvency, bankruptcy, end of the eligibility for coverage under COBRA, or involuntary termination of coverage.
 2. Persons who have experienced the loss of non-group health care coverage may apply for re-Enrollment in the Plan within six months of the loss of coverage due to insolvency, bankruptcy, or involuntary termination of coverage.
 3. Persons who have lost eligibility for Medicare full subsidy status, may apply for re-Enrollment in the Plan within six months of the change in eligibility status or loss of coverage.
 4. Persons who have become eligible for an Initial Enrollment Period for Medicare Part D because they are newly eligible for Medicare or who have become eligible for a Medicare Special Enrollment Period because they have involuntarily lost coverage under a Creditable Coverage Plan may apply for re-Enrollment in the Plan within six months of the change in eligibility status or loss of coverage.
- (b) A Member whose enrollment is involuntarily terminated under 651 CMR 15.13(2) may apply for re-enrollment in the Plan only during the period beginning April 1, 2001 and ending on March 31, 2002 or during Open Enrollment with the following exceptions:
1. Persons whose enrollment has been terminated under 651 CMR 15.13(2)(e) are prohibited from re-enrollment.
 2. Persons whose enrollment has been terminated under 651 CMR 15.13(2)(a) may apply for re-enrollment within six months after the occurrence of the following:
 - a. the re-establishment of residency in the Commonwealth; or
 - b. loss of MassHealth pharmacy benefits.
- (c) In the event that the Secretary closes Enrollment, no one shall be allowed to apply for re-enrollment until Enrollment re-opens.

15.06: Enrollment Process

(1) Application forms.

- (a) Application forms shall be made available through the Plan, through Elder Affairs and at locations frequented by potential Applicants.
- (b) A toll-free telephone number shall be available to provide Enrollment assistance and to take requests for application forms, and the telephone number shall conspicuously appear on application forms and other written materials regarding the Plan.
- (c) The Plan shall publicize that assistance with the application process is available to Applicants with limited English proficiency.

- (d) The Applicant or the Applicant's designee must complete and sign the application form and attest that all information submitted in the application form is true to the best of his or her knowledge and belief.
- (e) An application form may be submitted by mail or any other acceptable method as determined by the Plan.

(2) Applicant Information.

- (a) The Applicant must furnish his or her name, address and other information as specified by the Plan. The Plan may require verification of any eligibility requirement as deemed reasonable by the Plan.
- (b) Residency.
 - 1. As a condition of eligibility, an Applicant or Member must:
 - a. live in the Commonwealth with the intent to remain permanently or for an indefinite period; and,
 - b. whenever absent, intend to return to the Commonwealth.
 - 2. An Applicant must attest on the application form to his or her residence in the Commonwealth.
 - 3. Verification of residence may be required if there is conflicting or contradictory information regarding the Applicant's or Member's declared place of residence. In the event such information is required, residency shall be verified by the Applicant or Member by the submission of such documentation as deemed reasonable by the Plan.
- (c) Medicare Eligibility. As a condition of enrollment in the Plan, all Applicants who are eligible for Medicare must be enrolled in a Medicare Part D Plan or Creditable Coverage Plan. As an additional condition of enrollment in the Plan, all applicants who may qualify for the Low-income Subsidy, as determined by the Plan, shall apply for that subsidy. If authorized by the Applicant, the Plan may apply for the Low-income subsidy on his or her behalf.

(3) Age and Disability Status.

- (a) An Applicant under 651 CMR 15.04(1)(a) must:
 - 1. have reached his or her 65th birthday by the Effective Date of Coverage; and,
 - 2. attest to his or her age on the application form.
- (b) An Applicant under 651 CMR 15.04(1)(b) under age 65 must:
 - 1. verify disability status by submitting one of the following:
 - a. a current Social Security Administration (SSA) award letter for Social Security Disability Income (SSDI) or Supplemental Security Income (SSI) benefits;
 - b. a copy of the Applicant's Medicare card;
 - c. a certificate of blindness from the Massachusetts Commission for the Blind;
 - d. a copy of the determination of disability from MassHealth or CommonHealth; or
 - e. written verification of SSDI or SSI benefits signed by an authorized Social Security Claims Representative on Social Security letterhead.
 - 2. attest that he or she does not work more than forty (40) hours per month; and,

3. provide documentation consistent with 651 CMR 15.06(5) to verify that Applicant's Gross Annual Household income is not more than the Plan's designated percentage of the Federal Poverty Level for full Plan contribution toward Premiums and Deductibles.

(4) Membership Categories.

- (a) The Plan will establish Membership Categories based on Members' eligibility for Medicare Part D coverage, Gross Annual Household Income, and eligibility for the Medicare Low-income Subsidy. The Plan will annually define the specific benefit levels available to members in each category, including applicable Enrollment Fees, Co-Payments, Deductibles, Supplemental Assistance, and Annual Out-Of-Pocket Spending Limits. Applicants eligible under 651 CMR 15.04(1)(a) must submit financial information pursuant to 651 CMR 15.06(5).
- (b) Applicants determined to be eligible shall be enrolled into the Plan in the applicable Membership Category.
- (c) An Applicant or Member who has been determined by the Plan to be potentially eligible for the Low-income Subsidy, but who has not applied for or cooperated in the submission of an application for the Low-income Subsidy, may be temporarily classified in a Membership Category which offers no supplemental assistance for Premiums, and the lowest supplemental assistance for Co-payments and Deductibles.
- (d) A Member may at any time request in writing a Membership Category change by submitting financial information in accordance with 651 CMR 15.06(5). The Plan shall render a determination regarding the category change request after reviewing the Member's submitted financial information. The effective date of an approved category change is the first (1st) calendar day of the month following the date such a request is submitted to the Plan. A Member will not receive any refund for, or adjustment to, Premiums billed before a Member's request for a category change is submitted to the Plan.

(5) Income.

- (a) All Applicants must submit the following documentation of their income, as must all Applicants and Spouses who live together in the same housing unit:
 1. The most recently filed federal income tax return(s) and documentation of any additional Social Security income or;
 2. if the Applicant or his or her Spouse did not file a federal income tax return within the two years prior to application, easily obtainable means of income verification as approved by the Plan and indicated in the Plan's Application materials,

(6) Eligibility Determination.

- (a) Written notification shall be mailed to each Applicant or his or her authorized representative regarding the Plan's determination of eligibility for enrollment in the Plan, in the applicable Membership Category, and the Applicant's Effective Date of Coverage, if applicable.
- (b) The Plan shall only consider completed application forms. The Plan shall approve and enroll new Members on the first calendar day of each month.
- (c) An Applicant shall be notified in writing by the Plan regarding the determination of eligibility within forty (40) Business Days after receipt of a completed application form.
- (d) Application Form Review.

1. Eligible Applicants.

a. The Plan shall determine whether an Applicant meets eligibility criteria and shall enroll new Members in the Plan at the appropriate Membership Category according to his or her Gross Annual Household Income.

b. The Plan shall mail written notice to each Applicant or his or her authorized representative regarding the Plan's determination of eligibility for enrollment in the Plan, the Effective Date of Coverage, the Applicable Membership Category, any applicable Enrollment Fee, Premium, Co-Payments, and Deductibles.

2. Ineligible Applicants.

The Plan shall mail written notice to all Applicants or their authorized representatives determined to be ineligible for the Plan, including a summary of the determination, the reasons for the determination and the regulatory and/or legal citations supporting the determination.

3. Incomplete Application Forms.

a. If an Applicant fails to provide information necessary for the determination of eligibility, the Plan shall mail written notification to the Applicant or his or her authorized representative within fifteen (15) Business Days from the receipt of the application form regarding all outstanding information and/or documents that must be submitted in order to determine eligibility and be given the opportunity to complete or amend the application form.

b. If an Applicant fails to provide all outstanding information and/or documents necessary for the determination of eligibility within 60 days of a written notification as set forth in 651 CMR 15.06 (6)(d)3.a., the Applicant shall be determined to be ineligible for the Plan.

c. In the event that the Secretary closes Enrollment, the Plan may suspend all processing of incomplete application forms and/or modify timelines for notification or action on incomplete application forms until the Secretary has made a determination to re-open Enrollment.

15.07: Payment

(1) Membership Category Contribution Schedule.

(a) Contribution Schedules for Premium Contributions, Enrollment Fees, Co-payments, Deductibles, and Out-of-pocket spending limits shall be established by the Plan and supplied to all Applicants and may be made available to other interested parties upon request.

(b) One rate schedule shall apply to single Members, married Members whose spouses are not Members of the Plan, and married Members who do not live in the same housing unit as their spouses; the Plan may establish a separate rate schedule to apply to married Members whose spouses are Members of the Plan and live in the same housing unit. For Members enrolled in a Medicare Part D Plan, there shall be no separate contribution schedule based on marital status.

(c) Each Member or his or her authorized representative shall be notified in writing of any applicable Enrollment Fee, Premium, Co-payments, and Deductible.

(d) The Plan shall establish Enrollment Fee, Premium, Co-payment, and Deductible schedules annually. Written notification regarding changes to Members' Enrollment Fee, Premium, Co-payment and Deductible rates shall be mailed by the Plan to all affected Members or their authorized representatives at least 30 calendar days before the effective date of the change.

(e) The Secretary shall modify Enrollment Fee, Premium, Co-payment, and Deductible schedules and income eligibility levels after making a written determination that Plan expenditures are projected to exceed the amount appropriated for the Plan or, based on not less than nine months of claims and enrollment data for the current Fiscal Year, expenditures in the subsequent Fiscal Year are clearly projected to annualize beyond the expenditures projected by Elder Affairs in the subsequent Fiscal Year.

(2) Premiums and Enrollment Fees.

(a) Premiums shall be due on the twenty-fifth (25th) day of each month for coverage beginning the first (1st) calendar day of the following month. If the twenty-fifth (25th) day of the month is not a Business Day, the twenty-fifth (25th) day shall be deemed to be the next Business Day. Written notice shall be mailed to any Member, or his or her authorized representative, who has an overdue payment.

(b) If no Premium payment is received by the twenty-fifth (25th) day of the second month following the initial date on which the Premium payment is due, coverage shall terminate as of the first (1st) calendar day of the following month. If the twenty-fifth (25th) day of the second month is not a Business Day, the twenty-fifth (25th) day shall be deemed to be the next Business Day. Advance written notice shall be mailed to any Member or his or her authorized representative regarding termination of coverage for non-payment of Premiums.

(c) Enrollment Fees shall be due upon initial enrollment, and thereafter on December 1 of each year for coverage beginning January 1 of the next calendar year. Written notice shall be mailed to each member, or his or her authorized representative, of the upcoming due date.

(d) If the annual enrollment fee is not paid in full within thirty days after the due date, coverage shall terminate the first day of the following month. Advance written notice shall be mailed to any Member or his or her authorized representative regarding termination of coverage for non-payment of the Enrollment Fee.

(e) A Member whose enrollment has been terminated pursuant to 651 CMR 15.07(2)(b) or (d) may:

1. have their coverage reinstated by paying the total outstanding Enrollment Fee or Premium balance, including the Premium for the following month, within twenty-five (25) calendar days after termination; such reinstated coverage shall resume on the first (1st) calendar day of the month following payment, or
2. re-join only during Open Enrollment if the payment of any outstanding Premium balance is not made within twenty-five (25) calendar days of termination; prior to re-joining during Open Enrollment, any outstanding Premium balance must be paid and the Member may be subject to a surcharge.

(e) The Plan may seek collection of any outstanding Premium balance.

(3) Deductibles.

When acquiring Covered Benefits, Members are responsible for the payment of the Deductible applicable to the Member. For Members enrolled in a Medicare Part D Plan, supplemental assistance may be provided for the deductible required by the Medicare Part D Plan.

(4) Co-payments.

After a Member meets his or her applicable Deductible amount, he or she shall pay his or her Co-payment for each purchase of a Covered Benefit from a Participating Pharmacy or approved mail service facility until the Deductible is re-calculated or until the Annual Out-of-Pocket Spending Limit is met.

(5) Limitation on Member Out-of-Pocket Expenditures (Annual Out-of-Pocket Spending Limit).

(a) Once a Member's Annual Out-of-Pocket Spending Limit is reached, the Plan will cover the entire cost of Covered Benefits for that Member for the remainder of the Plan Year.

(b) The following are excluded from any calculation to determine a Member's Annual Out-of-Pocket Spending Limit:

1. Plan contributions as set forth in 651 CMR 15.06(4);
2. Member Premium payments and Enrollment Fees;
3. Non-covered costs paid by a Member, including, but not limited to:
 - a. expenses paid by a Member for Prescription Drugs prior to the Member's Effective Date of Coverage;
 - b. expenses paid by a Member for Prescription Drugs not covered by the Plan and/or;
 - c. co-payments, deductibles, premiums and coinsurance paid by a Member for Prescription Drugs acquired through any other plan. For Members of a Medicare Part D Plan, co-payments, deductibles and co-insurance paid pursuant to the Medicare Part D Plan will be included in a calculation to determine the Member's Annual Out-of-Pocket Spending Limit.

(6) Surcharge.

The Secretary may impose a surcharge for eligible persons who join during Open Enrollment.

15.08: Formulary. This section applies only to the Formulary developed and maintained by the Plan. Members of a Medicare Part D Plan shall refer to their Medicare Part D Plan Formulary to determine its rules and the included Prescription Drugs.

(1) The Plan will develop and maintain a Plan Formulary consisting of a list of Prescription Drugs. The Plan Formulary shall include insulin and disposable insulin syringes and needles. The Plan shall maintain a toll-free telephone number during business hours through which an Applicant or Member or his or her authorized representative may determine whether a particular Prescription Drug is included on the Plan Formulary.

(2) The Plan shall review the Plan Formulary and modify it as appropriate.

(3) The Plan shall not exclude any Prescription Drug from the Plan Formulary unless a Therapeutically Equivalent Prescription Drug is included on the Plan Formulary; however, the Secretary may exclude certain outpatient Prescription Drugs or classes of outpatient Prescription Drugs upon a written determination pursuant to G.L. 19A, §39(r) that the exclusion is necessary to maintain the fiscal viability of the program.

(4) Excluded from the Plan Formulary are Prescription Drugs labeled “Caution – limited by federal law to investigational use” or experimental drugs.

(5) To ensure appropriate use of Covered Benefits, the Plan may require Prior Authorization and/or implement benefit management tools, including quantity limitations for certain Prescription Drugs.

(6) Members shall have the right to seek a Review of the following:

- (a) a Member’s request to obtain a Non-Preferred drug at the Co-payment level of a Preferred Drug;
- (b) a Member’s request to add to the Plan Formulary a Prescription Drug excluded from the Plan Formulary; or
- (c) a Member’s request to gain access to a Prescription Drug excluded from the Plan Formulary at Plan Formulary rates.

15.09: Coordination of Benefits

(1) A Member shall have access to Covered Benefits under the Plan only after said Member has exhausted all other prescription drug coverage, including all coverage available under the Member’s Medicare Part D Plan or Creditable Coverage Plan.

(a) For Members with coverage under a Medicare Part D Plan or Creditable Coverage Plan, the Plan shall coordinate benefits by providing Supplemental Assistance as established for the applicable Membership Category.

(b) For Members who are not eligible for Medicare Part D coverage, but have another form of Prescription Drug Coverage, if a Prescription Drug is not a Covered Benefit under the other Prescription Drug coverage, but is a Covered Benefit under the Plan, the Plan will be the primary payor for that Prescription Drug.

15.10: Mail Service

(1) Mail service distribution of Maintenance Drugs shall be administered by the Plan and the Plan may require the use of said mail service.

(2) Any such mail service shall dispense Maintenance Drugs by an approved delivery service upon the Member’s submission of a Prescription and applicable payment to the Plan’s mail service facility.

(3) A Member may apply to be exempt from any mail service requirement of the Plan upon a showing that mail service would be inappropriate for the Member for medical or safety reasons.

Supporting information may include a written certification by the Member's physician, satisfactory to the Plan, that the use of such mail service would be medically inappropriate for the Member due to a disability or other significant limiting factor.

(4) For Members of a Medicare Part D Plan, the availability of mail service will be determined by the Medicare Part D Plan.

15.11: Applicant and Member Responsibility

(1) Applicants and Members, or their authorized representatives, must provide the Plan with the information necessary to establish or maintain enrollment.

(2) A Member or his or her authorized representative must report in writing to the Plan within fifteen (15) Business Days any changes that may affect eligibility or a Membership Category determination. These changes include, but are not limited to, changes in residence, marital status, disability status, Medicare eligibility, eligibility for the Low-income Subsidy, income, Prescription Drug coverage, and MassHealth coverage, including CommonHealth.

(3) If the Plan determines that a Member may qualify for the Low-income Subsidy, the Member must apply for that subsidy and provide the Plan with any documentation the Plan may reasonably request to verify the application.

(4) Beginning January 1, 2006, a Member who receives the Low-income Subsidy, must annually re-apply for that subsidy as required by the Social Security Administration, and must provide the Plan with any documentation the Plan may reasonably request to verify the re-application.

(5) If the Member's file is selected for audit and/or review, he or she must cooperate with the Plan to carry out the purpose of the audit and/or review.

(6) Failure of an Applicant or Member to fulfill any of their responsibilities set forth in 651 CMR 15.11 may result in the denial or termination of enrollment, or, for Applicants or Members who may be eligible for the Low-income Subsidy but fail to notify the Plan that they have applied for it, classification in a Membership Category that offers no supplemental assistance for premiums, and the lowest supplemental assistance for Co-payments and Deductibles.

15.12 Re-determination

(1) The Plan shall periodically conduct Member re-determination for the purpose of confirming a Member's eligibility and/or changing a Member's Membership Category and applicable, Premium, Enrollment Fee, Co-payments, and Deductible.

(a) The Plan shall mail a written notice to each Member or his or her authorized representative informing him or her of the re-determination requirement.

(b) Each Member or his or her authorized representative is required to complete a re-determination form and submit it and any required documentation to the Plan within thirty (30) Business Days from receipt of the re-determination notice. If a Member or his or her authorized representative fails to submit a complete re-determination form and required documentation within thirty (30) Business Days of receipt of the notice, the Plan may terminate the Member's enrollment as of the first day of the following month.

(c) If a Member or his or her authorized representative fails to submit a complete re-determination form and any required documentation within twenty (20) Business Days from receipt of the re-determination form, the Plan shall mail a reminder informing the Member or his or her authorized representative that the required information must be submitted to the Plan.

(d) Beginning January 1, 2006, if a Member who has been determined to be eligible for the Low-Income Subsidy, but fails to re-apply for that subsidy as required by the Social Security Administration or fails to provide the Plan with verification of his or her re-application for that subsidy, the Plan shall mail a written Notice informing the Member or his or her authorized representative that the required information must be submitted to the plan within thirty (30) Business Days of receipt of the notification. In the event a Member or his or her authorized representative fails to submit a documentation of the re-application for the Low-Income Subsidy within twenty (20) Business Days from receipt of the first, the Plan shall mail a reminder informing the Member or his or her authorized representative that the required information must be submitted to the plan.

(e) If a Member or his or her authorized representative fails to submit required documentation of the Member's reapplication for the Low-income Subsidy within thirty (30) Business Days of receipt of the Notice, the Plan may, prior to terminating the Member, reclassify the Member, as of the first day of the following month, in a Membership Category which offers no supplemental assistance for premiums, and the lowest supplemental assistance for Co-payments and Deductibles.

1. If a Member's enrollment is terminated due to a failure to submit a complete re-determination form and required documentation, the Member or his or her authorized representative may apply for re-enrollment only during Open Enrollment.

2. Members or their authorized representatives shall have the right to seek Review of a termination of enrollment due to a failure to submit a complete re-determination form.

(2) The Plan shall evaluate the information submitted by a Member or his or her authorized representative to confirm a Member's eligibility and/or adjust a Member's applicable Premium, Enrollment Fee, Co-payment levels and Deductibles, and Annual Out-of-Pocket Spending Limit.

(3) The Plan will notify the Member in writing of the re-determination decision and the Member's applicable Premium, Enrollment Fee, Co-payments, Deductible, and Annual Out-of-Pocket Spending Limit.

15.13: Termination

(1) Voluntary Termination of Enrollment.

A Member or his or her authorized representative may request in writing at any time that his or her enrollment in the Plan be terminated. Such termination shall be effective as of the first calendar day of the month following receipt by the Plan of the written request. The Plan shall mail written confirmation to the Member or his or her authorized representative regarding such termination from the Plan. In the event of such termination, the Member shall not be reimbursed for Premiums or other payments previously paid to the Plan by the Member.

(2) Involuntary Termination of Enrollment.

The Plan may terminate the enrollment of a Member and render a written determination which sets forth the legal, regulatory and/or policy basis for such determination, for any of the following reasons:

- (a) a determination that a Member no longer meets the eligibility standards set forth in 651 CMR 15.04;
- (b) non-payment of Premiums or Enrollment Fees pursuant to 651 CMR 15.07(2);
- (c) failure to comply with requirements under 651 CMR 15.11;
- (d) failure to submit re-determination information under 651 CMR 15.12;
- (e) a finding that a Member has committed fraud under 651 CMR 15.16;
- (f) mail sent to a Member or his or her authorized representative is returned as undeliverable with no forwarding address and other reasonable attempts to locate the Member have failed.

15.14: Notification

(1) All notifications issued by the Plan shall include information regarding an Applicant's or Member's rights to Review. Unless otherwise provided in these regulations, notice will be issued at least ten (10) business days in advance of the action to be taken by the Plan.

(2) Written notification shall be mailed by the Plan to an Applicant or Member or their authorized representative regarding the following:

- (a) an Applicant's submission of an incomplete Application form;
- (b) the determination of a Member's Membership Category, and applicable Enrollment Fee, Premium, Co-payments, Deductible; Effective Date of Coverage; or continued enrollment in the Plan;
- (c) the voluntary or involuntary termination of a Member's enrollment;
- (d) a Member's failure to make a timely Enrollment Fee or Premium payment;
- (e) the denial of Prior Authorization for Covered Benefits;
- (f) any Plan change regarding Membership Category and applicable Enrollment Fees, Premiums, Co-payments or Deductibles;
- (g) the Re-determination process and confirmation of a Member's status;
- (h) a Reconsideration determination made by the Plan; and,
- (i) an Administrative Review determination made by the Plan.

(3) Any written notification rendered by the Plan pursuant to 651 CMR 15.00 *et seq.* shall be deemed received three (3) Business Days after deposit in the U.S. mail, first class mail, postage pre-paid.

(4) Any written notification required by this section shall comply with applicable federal and state law regarding communication accessibility.

(5) At the written request of an Applicant or Member, all written material mailed by the Plan shall be sent to the Applicant's or Member's authorized representative.

15.15: Review

An Applicant or Member, or his or her designee, may seek Review of a Plan decision. An Applicant or Member may be assisted by his or her designee. Prescription Advantage will not provide review of any determination made by a Medicare Part D Plan, and members of those plans must seek review through those plans. Review consists of the following:

(1) Customer Service.

The Plan shall maintain a customer service center accessible toll-free by telephone (including TTY services) to assist Applicants and Members to resolve any issue regarding the Plan. Said customer service center shall comply with applicable federal and state law regarding communication accessibility. Contacting Customer Service is not a required step in seeking review of a Plan decision.

(2) Reconsideration.

(a) An Applicant or Member, or his or her designee, may request Reconsideration of a decision made by the Plan to deny or terminate enrollment, the Plan's determination of a Member's Gross Annual Household Income, or a decision by the Plan to deny or limit Covered Benefits. A request for Reconsideration is the first step in the review process. Such requests must be made in writing to the Plan.

(b) When an Applicant or Member, or his or her designee, requests Reconsideration of a decision made by the Plan to deny enrollment in the Plan pursuant to 651 CMR 15.06(6), or to terminate enrollment in the Plan pursuant to 651 CMR 15.13, such request must be made in writing and be received by the Plan within fifteen (15) Business Days after the Applicant's or Member's receipt of such decisions rendered by the Plan.

(c) Upon receipt of an Applicant's or a Member's request for Reconsideration pursuant to 651 CMR 15.15(2)(a) or (b), a designated Plan representative shall review the Applicant's or Member's enrollment file and attempt to resolve any outstanding issues.

(d) The designated Plan representative shall make a determination regarding an Applicant's or Member's request for Reconsideration according to applicable statutes, regulations and/or Plan policies.

(e) Within fifteen (15) Business Days after receiving a request for Reconsideration, the Plan shall mail to the Applicant or Member, or his or her designee, a written notice setting forth the Reconsideration determination, including the regulatory and/or legal citations and policy basis supporting the determination and a Member's right to an Administrative Review, if applicable.

(3) Administrative Review.

(a) Overview.

1. A Member, an Applicant, or his or her designee, may seek an Administrative Review of an adverse Reconsideration determination. Such determinations include, but are not limited to:
 - a. a denial of a Member's request to obtain a Non-Preferred Drug at the Co-payment level of a Preferred Drug;
 - b. a denial of a Member's request to add to the Plan Formulary a Prescription Drug excluded from the Plan Formulary;
 - c. a denial of a Member's request to gain access to a Prescription Drug excluded from the Plan Formulary at Plan Formulary rates; or
 - d. a denial of a Member's request to be exempt from any required Plan mail service program pursuant to 651 CMR 15.10(1).
 2. A Member, an Applicant, or his or her designee, may seek an Administrative Review only after pursuing Reconsideration pursuant to 651 CMR 15.15(2).
 3. To preserve the right to an Administrative Review, a Member or Applicant, or his or her designee, must respond to the Plan in writing within fifteen (15) Business Days after the Plan's written notification of its Reconsideration finding is received by the Member.
 4. The Administrative Review shall be conducted by an Administrative Review Officer. An Administrative Review Officer shall:
 - a. have no prior involvement in any matter related to the Member's or Applicant's issue under Administrative Review; and
 - b. have no direct or indirect financial interest, personal involvement or bias in any matter related to the Member's or Applicant's issue under Administrative Review.
- (b) Administrative Review Process.
1. Unless a Member or Applicant requests that a determination be made on the written record as submitted, the Administrative Review Officer shall schedule an Administrative Review meeting. The Member or Applicant, or his or her designee, may attend the Administrative Review meeting in person or by telephone. The Member or Applicant, or his or her designee, may present any oral or written information to support his or her request. The Plan shall also be permitted to appear at the meeting in person or by telephone and present any oral and written information in support of its decision.
 2. An Administrative Review meeting ordinarily will be scheduled no later than thirty (30) Business Days after receipt of a request for an Administrative Review.
 3. Information.
 - a. The Plan and Members or Applicants must submit to the Administrative Review Officer all materials supporting their position no later than the conclusion of the scheduled Administrative Review.
 - b. In the case of a request for Administrative Review according to 651 CMR 15.15(3)(a)1.a, such information must include, but not be limited to:
 - 1) written certification issued by the Member's physician that the Non-Preferred Drug is medically necessary and that there is no therapeutically equivalent Preferred Drug or Generic Drug available to the Member on the Plan Formulary; and,

- 2) documentation satisfactory to the Administrative Review Officer exhibiting that the Co-payment for the Non-Preferred Drug would create a financial hardship to the Member.
- c. In the case of a request for Administrative Review according to 651 CMR 15.15(3)(a)1.b or 1.c, such information must include, but not be limited to:
 - 1) a written certification issued by the Member's physician that the Prescription Drug excluded from the Plan Formulary is medically necessary and that there is no therapeutically equivalent Prescription Drug available to the Member on the Plan Formulary; and,
 2. documentation satisfactory to the Administrative Review Officer exhibiting that payment for such drug would create a financial hardship to the Member.
- d. In the case of a request for Administrative Review according to 651 CMR 15.15(3)(a)1.d, such information must include, but not be limited to a written certification issued by the Member's physician that due to a disability or other significant limiting factor, the use of the required Plan mail service program pursuant to 651 CMR 15.10(1) would be medically inappropriate for the Member, or that it should not be required in order to protect the safety of the Member.
- e. The Administrative Review Officer may, in his or her discretion, find that additional information is required prior to rendering a determination, including but not limited to written and verbal information. In such cases, the Administrative Review Officer shall inform the Plan and/or the Member or Applicant, or his or her designee, that they have no more than ten (10) Business Days to submit applicable written information to the Administrative Review Officer. The Administrative Review Officer shall forward such additional information to the non-submitting party and allow five (5) Business Days for that party to respond.
- f. Members or Applicants who fail to comply with the information requirements of 651 CMR 15.15(3)(b)3 in a timely manner may be subject to an adverse determination.

4. Determination.

- a. The Administrative Review Officer shall examine the information provided during the Administrative Review process and render a final written determination. Said determination shall be made in accordance with applicable statutes, regulations, and policies governing the Plan. The written determination shall set forth the legal, regulatory and/or policy basis for such determination, and the action, if any, to be taken by the Plan.
- b. The Administrative Review Officer shall mail the written determination , to the Member or Applicant, or his or her designee, and the Plan within twenty (20) Business Days of the receipt of the last submitted information from the Member or Applicant or the Plan.

15.16: Fraud

Any person who obtains coverage by knowingly and deliberately making false statements, suppressing facts, withholding information or making misrepresentations, commits fraud and is subject to recovery of the amount that the Plan has paid on that person's behalf and any other

penalties permitted or prescribed by law. Those found to have committed fraud forfeit the right to re-join the Plan.

15.17: Recovery

The Plan may recover the cost of Covered Benefits that a Member was not entitled to receive, or for which a Member was not eligible, regardless of who was responsible for the overpayment and whether or not there was any fraudulent intent.

REGULATORY AUTHORITY

651 CMR 15.00: St. 2000, C. 159 §§ 46, 47, 406 AND 497 (as amended by St. 2001, c. 177, § 11).